

reconstitution of radiopharmaceutical kits;

(b) Bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;

(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use;

(d) Check survey instruments and dose calibrators as described in §§35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use;

(e) Carry a radiation detection survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed;

(f) Retain a record of each survey required in paragraph (e) of this section for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

#### **§35.90 Storage of volatiles and gases.**

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

#### **§35.92 Decay-in-storage.**

(a) A licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of §20.2001 of this chapter if it:

(1) Holds byproduct material for decay a minimum of ten half-lives;

(2) Monitors byproduct material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished

from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section for three years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

### **Subpart D—Uptake, Dilution, and Excretion**

#### **§35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.**

A licensee may use for uptake, dilution, or excretion studies any unsealed byproduct material prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §35.920, or an individual under the supervision of either as specified in §35.25.

[59 FR 61784, Dec. 2, 1994]

#### **§35.120 Possession of survey instrument.**

A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.